

From: Rosen, Bailey [Rosen.Bailey@epa.gov]
Sent: 12/22/2020 9:54:54 PM
To: Bolen, Derrick [bolen.derrick@epa.gov]; Collazo Reyes, Yvette [CollazoReyes.Yvette@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Drinkard, Andrea [Drinkard.Andrea@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Fischer, David [Fischer.David@epa.gov]; Giddings, Daniel [giddings.daniel@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Hughes, Hayley [hughes.hayley@epa.gov]; Kaiser, Sven-Erik [Kaiser.Sven-Erik@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Kochis, Daniel [Kochis.daniel@epa.gov]; Labbe, Ken [Labbe.Ken@epa.gov]; Layne, Arnold [Layne.Arnold@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]; Mills, Madeline [Mills.Madeline@epa.gov]; Nguyen, Khanh [Nguyen.Khanh@epa.gov]; OPS CSID CB [OPS_CSID_CB@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; Richmond, Jonah [Richmond.Jonah@epa.gov]; Siciliano, CarolAnn [Siciliano.CarolAnn@epa.gov]; Sullivan, Melissa [sullivan.melissa@epa.gov]; Tyler, Tom [Tyler.Tom@epa.gov]; Vendinello, Lynn [Vendinello.Lynn@epa.gov]; Vernon, Jennifer [Vernon.Jennifer@epa.gov]
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Five Toxic Chemicals Get Sales, Production Limits From EPA (1)

Pat Rizzuto, Bloomberg Law

<https://news.bloomberglaw.com/environment-and-energy/sales-production-limits-for-five-toxic-chemicals-set-by-epa>

The EPA is banning or significantly restricting five particularly troublesome chemicals used in the electronics, petroleum, plastics, rubber, and other industries.

The Environmental Protection Agency issued final rules Tuesday for controlling five chemicals, including HCBD, or hexachlorobutadiene, which is unintentionally produced as a byproduct when chlorinated solvents are made.

Its regulation is the regulatory package's main surprise. The agency had proposed to conclude restrictions weren't needed as other federal and state regulations control the chemical.

All five chemicals persist in the environment for many years, build up in the food chain, and are toxic, and are called PBTs. A special section of the 2016 Toxic Substances Control Act amendments required the EPA to restrict all five chemicals—or explain why it didn't—by the end of this year.

"By working with a wide variety of stakeholders, we were able to put in place restrictions on five PBT chemicals that will protect our families and our environment," said Alexandra Dapolito Dunn, head of the agency's Office of Chemical Safety and Pollution Prevention.

The other four chemicals are:

two flame retardants: decabromodiphenyl ether, or DecaBDE; and phenol, isopropylated phosphate (3:1), or PIP (3:1);

pentachlorothiophenol (PCTP), which is used to make rubber more pliable; and

2,4,6-tris(tert-butyl)phenol(2,4,6-TTBP) used as an additive in motor oils.

Flame Retardants

Most companies are banned from making decaBDE or using it in a wide range of products. They include plastic enclosures for televisions and other electronic equipment; textiles and upholstered articles, wire and cables for communication; and other applications, the EPA's rule (RIN 2070-AK34) said.

The ban applies to imports of the chemical and products made with it. The ban will largely kick in one year after the rule is published in the Federal Register.

Some industries, however, get more time to stop using decaBDE. These include the aerospace industry; factories making wire and cable insulation for nuclear power generation facilities; and companies making curtains with the chemical for the hospitality industry.

Production and use of PIP (3:1)—which is used to make motor oils, industrial coatings, and plastics in addition to helping prevent fires—generally are banned by its final rule (RIN 2070-AK58).

But the EPA's ban is phased in for some applications. They include using the chemical to make adhesives, sealants, and photographic printing products.

Companies making military-specification hydraulic fluids for the aerospace and certain other applications also can continue to use PIP (3:1) if no other alternative is available, the EPA said.

Golf Balls OK

Golf balls escaped the EPA's rule (RIN: 2070-AK60) for pentachlorothiophenol. The rule prohibits the production, import, processing, and distribution of PCTP and products made with it unless the chemical's concentrations are at or below 1% by weight.

The ban on domestic production won't change much, because that ended years ago, the EPA said. But PCTP has gotten into the country through imported products.

It also may have been getting into the U.S. as an impurity in the rubber cores of some golf balls, the EPA said. The core can improve the balls' spin, rebound, and distance.

The rule won't apply to old golf balls that remain on the market, the EPA said. The sole company making PCTP-containing golf balls provided data showing the amount was less than the agency's 1% threshold, the EPA said.

Some groups wanted the EPA to ban PIP (3:1) altogether, but the 1% threshold is a practical way to limit PCTP from being released into the environment, and encourage the use of alternative chemicals, the agency's rule said.

Fuel Additive

The final 2,4,6-TTBP rule (RIN 2070-AK59) prohibits mixing and distributing oils and lubricants with the chemical at concentrations greater than 0.3% five years after the regulation is published.

Companies can't use or distribute 2,4,6-TTBP as a fuel additive, fuel injector cleaner, or other products in containers less than 35 gallons, the EPA said. That ban also becomes effective five years after the rule is published.

The container size limit is designed to prevent use of such products by consumers and small auto repair, marina, or other shops, the agency said.

Unintentional Byproduct

The final HCBP rule (RIN 2070-AK61) prohibits the manufacturing, import, mixing, and distribution of the chemicals and products made with it.

The EPA recognizes the chemical can also be generated unintentionally as a byproduct when chemical makers produce solvents such as perchloroethylene, trichloroethylene, and carbon tetrachloride. The byproduct is typically burned as fuel, the EPA said.

The agency said the inadvertent production and burning of the byproduct are consistent with the approaches other countries are taking to limit HCBP releases. The chemical is included on a list of compounds that countries have agreed to phase out of production under the Stockholm Convention on Persistent Organic Pollutants.

Separately, the EPA is developing regulations to control perchloroethylene, trichloroethylene, and carbon tetrachloride. Its evaluation of the chemicals concluded they pose unreasonable risks, triggering regulations.

EPA proposes near doubling of TSCA fees for future risk evaluations

Terry Hyland, Chemical Watch

<https://chemicalwatch.com/195302/epa-proposes-near-doubling-of-tsca-fees-for-future-risk-evaluations>

The US EPA has proposed multiple changes to its TSCA fees programme, including hiking risk evaluation fees from \$1.35m to \$2.56m for each high-priority substance.

Under the proposal companies would be allocated their share of the costs based on the volume of the substance undergoing evaluation it produces.

The proposal would also add three new types of fees to the eight current categories, and expand the number of exemptions categories from the three it announced in March to six.

Proposed exemptions from TSCA fees would apply to companies that:

import a high-priority substance in an article;
produce a high-priority substance as a byproduct;
produce or import such a substance as an impurity;
produce one as a non-isolated intermediate;
only utilise a high-priority substance for research and development activities; or
manufacture less than 2,500lbs of such a substance.

The proposal – issued in pre-publication form on 21 December – is the opening step in the agency's reassessment of the 2018 rule that set out the TSCA fees structure. The law requires that the fees be reassessed and adjusted as necessary every three years, as needed.

The EPA did not propose changes to existing fees for TSCA section 4 testing or new substance applications under TSCA section 5, maintaining the current \$9,800 fee for test orders and the \$16,000 fee for new substance applications. The agency also said it was not proposing changes to its definition of small business entities, which remain eligible for an 80% discount on certain fees.

However, the EPA did add three additional types of activities to which fees would apply, including:

\$9,800 for amended test orders;

\$500 for a bona fide notice of intent to manufacture or import, used to obtain written determination of whether a chemical substance is included in the confidential inventory; and

\$500 for a notice of commencement of manufacture or import.

The agency will accept comments on the planned changes for 45 days following the proposal's formal publication in the Federal Register. A final rule is due in October 2021.

Companies potentially subject to the TSCA fees include manufacturers, importers, distributors, processors and entities required to submit information under sections 4 or 5 of TSCA. Potentially affected entities specifically mentioned by the EPA included chemical manufacturers, petroleum and coal companies and chemical, petroleum and merchant wholesalers.

Expanded fees and flexibility

The EPA said it used cost data gathered over the last two years, rather than estimates, to update the fee calculations.

Fees for future EPA-initiated risk evaluations would nearly double under the proposal, from \$1.35m per high-priority substance to \$2.56m. The agency also proposed additional fees for manufacturer-requested risk evaluations, with two payments, rather than one initial payment, required and a final payment due upon completion of the evaluation.

In addition to providing more exemptions from the fees, the agency also provided additional flexibility and time to pay.

The agency proposed allocating fees for a section 6 risk evaluation based on each large manufacturer's percentage of the total volume of the substance produced, after first allocating fees for small businesses.

"The EPA believes this approach for calculating TSCA section 6 fee allocations will result in a more representative distribution of fees and better account for the wide variation in production volume sometimes associated with a particular chemical substance," the agency said in the proposal, but it acknowledged that carving out small manufacturers from the calculation could result in those entities paying higher fees if they produce more than other manufacturers.

Extra time

The EPA also proposed additional time for companies to make the payments, with a two-part payment installment process.

Under the proposal, 50% of the fee assessed for a section 6 risk evaluation would be due within 180 days after the agency publishes the final scope of a chemical risk evaluation, with the remainder due 545 days after the final scope is published.

The 2018 rule called for the total amount of fees to be paid within 120 days, although the agency recently said it would allow companies subject to fees for the 20 chemicals currently undergoing TSCA risk evaluations to make 'incremental payments' with an extra eight months to pay the full amount.

The agency said it also would allow for corrections to be made to the list of manufacturers subject to EPA-initiated risk evaluations after the final list is published. This is what the EPA did this time around, publishing the final list of fee payers in September, and updating the list in late-November.

In addition to extra time to pay the risk evaluation fees, the agency's proposal would provide additional time for companies subject to fees for a section 4 test rule or a section 6 risk evaluation to form consortia to determine an equitable division of fee responsibilities. Companies would have 90 days – up from the current 60 days – to notify the EPA of their intent to form a consortium.

3 PFAS disposal technologies are most promising, US EPA says

Cheryl Hogue, Chemical & Engineering News

<https://cen.acs.org/environment/pollution/3-PFAS-disposal-technologies-promising/98/web/2020/12>

Three technologies offer the best potential for disposing of per- and polyfluoroalkyl substances (PFAS) while keeping these “forever chemicals” out of the environment, the US Environmental Protection Agency says.

PFAS are synthetic compounds that resist heat, harsh chemical conditions, or moisture, and they have broad applications in industry and society. Those same properties mean that they don't readily degrade in the environment, creating a challenge when it comes time for disposal.

Burning PFAS as hazardous waste to destroy the chemicals is one of the three technologies the EPA suggests in interim guidance issued Dec. 18. Commercial incinerators, cement kilns, and lightweight aggregate kilns “can potentially achieve temperatures and residence times sufficient to break apart the PFAS contained in the waste stream being thermally treated,” according to the guidance.

But this technology has a big unknown—what's emitted into the air when these facilities burn PFAS. The EPA says it is gathering information to determine whether these facilities can adequately control potential products of incomplete combustion, including novel PFAS that could form during burning.

A second disposal technology the EPA selected is placing PFAS waste into landfills. Hazardous waste landfills that have extensive pollution controls, such as double liners, leak detection, and collection and treatment of leachate, are more effective at keeping PFAS waste out of the environment than municipal solid waste landfills, the guidance says.

Disposal of PFAS in landfills also has significant unknowns, the EPA says. These include how PFAS waste might interact with and affect the integrity of landfill liners and whether these chemicals might escape from landfills into the atmosphere.

The third technology is disposing of liquid PFAS into deep injection wells. However, a limited number of these disposal wells accept PFAS waste and the cost of transporting liquid waste to them could render this option impractical, the EPA says.

In addition, “Waste streams disposed of by underground injection will likely need to have low concentrations of suspended solids. This restriction may limit both the type and quantity of PFAS-related liquid waste streams,” the agency says.

“The EPA recognizes that many large data gaps exist regarding the full suite of disposal and destruction methods it outlines, including thermal destruction,” says Olga Naidenko, vice president for science investigations at the Environmental Working Group, an environmental advocacy nonprofit. “Many of these same scientific uncertainties and

concerns have been raised by communities on the frontlines of PFAS pollution for years.” Naidenko faults the EPA guidance for failing to “stop the environmental injustice of PFAS contamination in communities near the disposal sites.”

The EPA guidance applies to materials with PFAS, such as fire-fighting foams, that are not consumer products. Congress required the EPA to prepare the guidance on destruction and disposal of PFAS as part of the fiscal 2020 military spending law. That law directs the Defense Department to stop using fluorinated fire-fighting foams by Oct. 1, 2024. This marks the first guidance the EPA has provided on the disposal of any sort of PFAS.

FY21 Budget Seeks Science Rule Review, Presses EPA On Key Assessments

Maria Hegstad, Inside TSCA

<https://insideepa.com/tsca-news/fy21-budget-seeks-science-rule-review-presses-epa-key-assessments>

Congress’ fiscal year 2021 funding package for EPA and other agencies renews calls to subject the Trump administration’s science transparency rule to dual rounds of peer review, a process that could give the incoming Biden administration additional options for killing the controversial measure.

The omnibus funding package also provides EPA direction on several pending chemical assessments while also providing additional funds and oversight requirements for the agency’s ongoing research and remediation of per- and polyfluoroalkyl substances (PFAS).

The legislation, which must be enacted by Dec. 21 to avoid a government shutdown, provides EPA with \$9.237 billion for the remainder of FY21, a \$179 million increase over FY20 and \$2.53 billion increase over exiting President Donald Trump’s budget request.

The final top-line figure appears to be a compromise between the \$9.38 billion for EPA the Democratic House approved last summer and the flat funding of \$9.085 billion that the Senate proposed last month.

Sen. Tom Udall (D-NM), the ranking Democrat on the appropriations panel that funds EPA who is retiring at the end of this Congress, says in a Dec. 21 press statement that the bill also “rejects the Administration’s proposals to cut research by 38 percent” and provides an increase of \$2.3 million, or 24 percent, to EPA’s environmental justice program, a top priority for the incoming Biden administration.

The legislation also appears to raise concerns with the administration’s pending proposal to raise the bar on the data the agency can use to write rules in the future, a measure that many environmentalists and former agency officials are urging the next administration to rescind.

As first proposed in 2018, EPA’s “Strengthening Transparency in Regulatory Science” rule would require regulatory decisions to incorporate only studies and models whose underlying information is publicly available. But the agency later released a supplemental proposal floating a range of options that would allow consideration of studies that offer “tiered” access to underlying data, that rely on confidential and proprietary information, or “that cannot be sufficiently de-identified to protect” their subjects.

While the final rule has yet to be released, Administrator Andrew Wheeler said during a Dec. 9 event at the Heritage Foundation that officials “actually are narrowing it a little bit more” than what the agency has proposed to make sure it will not exclude “important science for regulations in the future.” He said he hopes it will be “unveiled in a couple of weeks.”

But the spending legislation directs the agency to provide an update, within 60 days, on the status of an order in FY20 spending legislation requiring EPA to contract with the National Academy of Sciences (NAS) to review the rule. The requirement, in report language attached to the FY20 legislation, directed EPA to broaden and finalize review of the proposed rule within EPA’s Science Advisory Board before finalizing it and also to contract NAS for additional review.

The NAS review “should assess the manner in which the rule alters the ability of the Agency to use publicly available peer-reviewed scientific and medical studies in its regulatory decision-making, including what the NAS considers to be the best available scientific information, and be completed within 270 days.”

Since EPA has yet to finalize the rule, the NAS study direction has yet to be triggered. And given scientists,' environmentalists' and Democrats' disdain for the rule and concerns over its ramifications, it seems likely the incoming Biden Administration will attempt to roll it back.

Chemical Assessments

The FY21 bill also highlights Congress' interest in EPA's efforts to assess chemicals' toxicity and risk, both within the revised Toxic Substances Control Act (TSCA) program, as well as the agency's Integrated Risk Information System (IRIS), the program within EPA's research office that has been conducting hazard identification and dose-response analyses for offices across the agency since the 1980s.

For example, the bill calls out the toxics office's ongoing TSCA evaluation of asbestos, one of the first 10 substances the Obama EPA selected for risk evaluation under the revised statute. "The Committees note that the Agency released a draft risk evaluation for asbestos in March 2020," the bill states. "As the Agency continues to find the high risks associated with exposure to asbestos, the Committees encourage the Agency to finalize the risk evaluation and report to the Committees as expeditiously as possible. The Agency must work with Congress to effectively protect communities from further exposure."

The bill does not mention the highly critical peer review of the "deficient" draft asbestos evaluation that EPA's Science Advisory Committee on Chemicals conducted last summer, or the bipartisan effort in the House Energy & Commerce Committee to ban asbestos use that failed in the fall over last-minute changes to appease Democratic constituents.

The committees also highlight the long-pending IRIS assessment of inorganic arsenic, with the bill stating that the committees "understand that a revised risk assessment of inorganic arsenic is currently under development by the Agency. The Committees note the importance of a robust evaluation of all relevant scientific data, including mode of action data. The Committees direct the Agency to brief the Committees if and when the revised risk assessment is completed."

Mode of action has been a long-standing issue stalling the arsenic IRIS assessment's completion, with industry and consultants urging EPA to accept evidence of a non-linear mode that would move the agency to depart from its traditional conservative approach to assessing cancer risk with any level of exposure providing some level of risk. EPA's last update from the IRIS program, released last October, indicates the program intends to issue a public draft assessment for comment in the second quarter of FY22.

The omnibus bill includes new compromise language on the IRIS program overall, which House Democrats have blamed the Trump administration for sidelining in favor of the rising TSCA program.

While report language attached to the House bill last summer provided extensive direction to the Trump EPA regarding reinstating the IRIS program and maintaining it separately within the research office, the new bill rescinds that language. Instead, it states simply, "the Committees direct the Agency to continue to utilize the IRIS program to support the Agency's mission to protect human health and the environment" -- a change that likely reflects the outcome of the 2020 presidential election.

The bill also offers its support to another program that has been sidelined in the Trump EPA, that of the Safer Choice green chemistry program within EPA's toxics office. The program is voluntary and provides technical assistance to interested industries looking to conduct alternatives analyses or cleaning product manufacturers looking to gain the positive publicity of having their products recognized by EPA's Safer Choice logo. But in the early years of EPA's efforts to implement the many new responsibilities and meet the many new deadlines of the revised TSCA, toxics leaders moved many of its scientists to details to assist the TSCA program, particularly in the new chemicals program.

The bill also provides significant new funding for EPA to address PFAS, a widening concern. The bill directs some \$49 million, a \$10 million increase above similar funding provided in FY20 "for environmental cleanup programs and related scientific research to help address contamination caused by PFAS chemicals and other contaminants of emerging concern, including not less than \$20 million in direct support for states," Udall's statement adds. Additionally, the bill directs EPA brief the committees on planned FY21 "PFAS-related actions and provide the Committees with a spend plan which details funding at the program project level."

The bill also boosts research funding, directing some \$20 million “for priority actions under the PFAS Action Plan, an increase of [\$2 million].”

EPA Seeks To Ease TSCA Fees But Environmentalist Fears Risk Effects

David LaRoss, Inside TSCA

<https://insideepa.com/tsca-news/epa-seeks-ease-tsca-fees-environmentalist-fears-risk-effects>

EPA’s plan for overhauling its TSCA fees program seeks to codify a set of short-term categorical waivers it enacted in response to the COVID-19 pandemic for current fee payments, as well as other regulatory relief and payment flexibilities sought by competing industry groups while also increasing the fees charged to industry.

But some environmentalists are already pushing back against many of the proposed changes, arguing that exempting any category of chemical users from TSCA fees amounts to an unlawful finding that those chemical uses pose no risk to workers or the general public -- a signal that they will likely push the Biden EPA to make major changes to the proposal or drop it entirely.

“EPA is making premature assumptions about the potential risks such chemicals would present so as to effectively prejudice and discount their risk evaluations. . . . There is no authority under TSCA for these exemptions, nor for the staggered payment schedule EPA is proposing, which will complicate its ability to hire staff and expend other resources needed to implement TSCA,” one environmentalist says.

The Dec. 21 proposal would change which companies must pay to support TSCA assessments of chemicals they use, manufacture, sell or import, as well as revising the formula by which EPA allocates the fees among liable firms.

EPA had -- on a short-term basis -- already begun allowing waivers for certain categories of manufacturers that import a chemical as part of an article, produce the substance as a byproduct in other processes, or produce or import the chemical under review as an impurity in other materials, in order to provide industry with fee relief during the COVID-19 pandemic.

The agency has signaled that it planned to make such waivers permanent as part of the fees proposal.

But the proposal also adds a series of additional exemptions that both downstream users and upstream manufacturers had sought in early comments on the rulemaking, including for firms that use a chemical only below a 2,500-pound de minimis threshold, exclusively for research and development purposes, or as an intermediary in the production of other substances.

And the proposal also adds several revisions to the original 2018 TSCA fee rule beyond new waivers, including adding a fee mandate for manufacturers who only produce a covered chemical for export, a measure sought by some domestic producers, and allocating fees among companies on the basis of production volumes -- addressing what several industry attorneys and groups have said is an unfair system for allocating payment responsibility.

Rather than the current formula of splitting fees equally among all responsible companies -- with a discount for small businesses -- the Dec. 21 proposal allows the agency to scale the firms’ fees due “based on their percentage of the average annual production volume from the four calendar years prior to the year certification was made.”

That could address what industry attorney Martha Marrapese, a partner with the law firm Wiley Rein, described in an Oct. 2 blog post as a fundamental flaw in the fee program.

“Companies are expected under EPA’s rule to pay no more than equal amounts of the total fee split among all of the participating companies. This means that a company who imports 6 pounds of a chemical is on the hook for the same amount as a company who manufactures 60 million pounds. Right now, these companies are facing fee payments on the order of \$50,000 to \$115,000,” she wrote.

‘Real-World Situations’

EPA in its announcement of the proposal says its plan “reflects real-world situations, narrows the broad scope of current requirements, significantly reduces the burden on American businesses, and increases the flexibility for surrounding TSCA fees requirements.”

But the environmentalist warns the exemptions the agency is proposing to provide could prevent EPA from being able to collect enough money in fees to fully cover the cost of a risk evaluation as the law requires.

“EPA has full authority to conduct risk evaluations on at least the latter two of the three new exemption categories,” referring to chemical intermediates and use under the 2,500-pound threshold, “and there is no reason to expect a priori the cost of those risk evaluations will somehow [be] less,” the source says.

In particular, the environmentalist continues, a de minimis threshold for fees “assumes lower volume can be assumed to mean lower risk without considering a host of issues: extent and nature of exposures, potency across all relevant hazards, etc.” For instance, engineered nanomaterials “can’t be simply assumed to be less risky” because of their small mass, the source says.

Similarly, chemical intermediaries -- those produced during a chemical reaction that are intended to be completely converted into other substances by the end of the process -- might not actually be completely eliminated, the source says, if some amount avoids the reaction or is released to the environment inadvertently. “In my experience, smaller-volume uses of chemicals whose primary use is as an intermediate are often overlooked. EPA is putting the cart before the horse to exempt this use up front from fees before examining these kinds of questions.”

Other changes include extending payment deadlines, such as opening the door to installment plans; revising the fees the agency will charge based on “cost data gathered over the last two years” of operating the program; and allowing companies to seek corrections to a final list of chemical users, among others.

And the agency would collect those fees in three installments rather than two as it currently does, giving companies further payment flexibility.

Finally, EPA is proposing to raise the amount it charges in fees in order to better reflect a risk evaluation of an existing chemical under TSCA section 6 when the study is initiated by EPA, as opposed to those undertaken at a manufacturer’s request -- from \$1,350,000 to \$2,560,000 for larger businesses, and from \$270,000 to \$512,000 for small firms.

The change is based on a series of factors, EPA says in the rule, including “increases to TSCA section 6 program cost estimates, decreases in the activity assumptions for TSCA section 5 submissions, early feedback received from industry stakeholders during the 2018 rulemaking, and to ensure EPA is able to defray 25% of the Agency’s cost” in conducting chemical assessments.

Unlike the other proposed changes, the environmentalist source says that shift is welcome. “EPA certainly had low-balled its cost estimate in the initial fee rule. But there is scant discussion I’ve found yet about that, and it may be buried in documents not yet available,” the environmentalist says.

Environmentalists Detail Tough Principles For Upcoming TSCA Regulations

Maria Hegstad, Inside EPA

<https://insideepa.com/daily-news/environmentalists-detail-tough-principles-upcoming-tsca-regulations>

Environmentalists are floating a set of tough principles they hope will guide EPA as it begins writing its first risk management rules under the revised TSCA, a move seen as pushing back on industry efforts to tailor such rules just as the Biden administration, which is expected to be more sympathetic to environmentalists’ views, takes office.

Developed by Safer Chemicals Healthy Families (SCHF) earlier this month, the document lays out what it describes as 12 “key principles that must guide EPA as it develops these rules.”

Based on statutory timelines spelled out in the 2016 reforms to the Toxic Substances Control Act (TSCA), the first TSCA section 6 rules will be proposed and finalized by the incoming Biden administration, to address any unreasonable risks the Trump EPA identifies in the first 10 risk evaluations it is seeking to complete before departing officials’ terms end on Jan. 20.

The document touches upon a number of areas of longstanding concern for environmentalists, for example, that EPA rules must eliminate all risk without concern for cost; that susceptible subpopulations must be fully protected; that EPA

should account for aggregate exposures in its rules; and that the agency should take immediate action to regulate chemicals deemed to pose serious and imminent risks.

But the document also includes some more detailed requests, such as a call for EPA to “account for and quantify all health benefits, including non-cancer health benefits” in the cost-benefit analyses that support its rules. That may be difficult as the agency’s current methods for assessing non-cancer risks -- such as cardiovascular, neurological and other risks -- do not lend themselves to quantifying benefits.

While all 12 principles may not previously have been included in a single document, environmentalists have detailed some of them in recent webinars EPA has held as it begins public consultations on how to write its upcoming risk management rules.

For example, they have called for bans on hexabromocyclododecane (HBCD) and related flame-retardant chemicals that are already subject to a global phase-out, exercise of emergency authority to quickly regulate some uses of methylene chloride, 1-bromopropane and trichloroethylene (TCE) and the revival of Obama-era proposals governing TCE that the Trump administration has shelved.

An environmentalist familiar with the principles tells Inside TSCA that the document was developed after talks with the agency suggested the need for a “framework” to guide the creation of risk management rules. “After a few discussions with EPA staff about its approach to risk management, it seemed that the Agency is struggling and that a high-level framework for translating risk evaluations into section 6(a) rules would be helpful,” the source says.

“This is just a first shot -- there are many more questions to be addressed -- and we’re not suggesting that the proposed principles should be codified in any formal way.”

Unified Agenda

Environmentalists’ approach contrasts with efforts by industry groups and the Trump administration to codify a process by which EPA would tailor its TSCA section 6 rules to address unreasonable risks, an approach that environmentalists have opposed.

EPA’s Fall 2020 unified agenda, released Dec. 9, formally announced a rulemaking that several industry groups sought: a framework process rule that would guide how the agency crafts risk management regulations under section 6.

The agenda explains that the agency “is developing a proposed procedural rule under [TSCA] for the management, by rule, for existing chemicals determined to present unreasonable risks. This procedural rule would present a transparent and consistent approach to EPA rulemaking under TSCA section 6(a).”

Five industry groups -- The Toy Association, American Coatings Association, National Association of Home Builders, National Association of Manufacturers, and U.S. Chamber of Commerce -- petitioned EPA to write such a framework procedural rule, saying such a measure is needed to codify the “tailored” approach the law requires when the agency crafts its regulations. But environmentalists charged that EPA lacks the authority to write such a rule and that the petition has an “agenda of circumscribing and narrowing” how the agency will exercise its discretion when it writes section 6 rules.

They are “asking EPA to make decisions that are very favorable” to industry and to “prejudge section 6 rules.” There is no benefit to EPA or the public in doing that, Robert Sussman, EPA’s former deputy administrator who now represents environmentalists, told Inside TSCA last summer.

Instead, SCHF has crafted the dozen principles that call on EPA in the TSCA section 6(a) rules it is writing to: “eliminate unreasonable risks, without regard to costs and other non-risk factors”; fully protect subpopulations at greater risk of greater susceptibility, increased exposure or other factors; “take immediate action to address imminent and serious risks presented by the 10 chemicals”; “account for . . . aggregate exposures in determining the level of protection necessary to provide adequate protection against the risk”; “create incentives to transition to safer, more sustainable alternatives” and ensure that “[w]here multiple regulatory options will effectively and reliably eliminate the unreasonable risk, EPA has broad discretion to select the most health protective option.”

Non-Cancer Risks

SCHF also addresses a longstanding concern among EPA staff and others: that the traditional regulatory risk analysis approach EPA and other agencies use to assess non-cancer risks will be difficult if not impossible to use as the basis for writing risk management rules.

“EPA must account for and quantify all health benefits, including non-cancer health benefits,” the document states, before suggesting short-term approaches EPA could use to address this issue.

EPA “can use existing approaches to calculate benefits but cannot assign a ‘zero’ value if monetary estimates for certain benefits are not available; in cases where benefits are known but not quantifiable, assuming zero benefits would not be scientifically supportable. The Agency should use a default value for these benefits, possibly based on a percentage of the statistical value of life.”

Such concerns have driven long-standing calls to unify how EPA conducts its chemical risk analyses so that non-cancer effects are assessed similarly to how cancer effects are currently analyzed. EPA’s traditional approach to quantifying non-cancer risk results in a “safe” dose not to be exceeded, which does not provide information useful to cost-benefit analysis.

Cancer risk analyses, however, provide a potency slope showing “safe” levels at various risk levels. Such information can be used to estimate costs and benefits of various regulatory options. Economists and other professionals at EPA and elsewhere have long argued that such information is needed so that EPA can more easily base rules on risks associated with non-cancer health effects, like neurological or cardiovascular harms.

“Many people -- including at EPA -- have perceived a need to better capture the benefits of reducing non-cancer risks of harm. These risks (immunotoxicity, neurotoxicity and repro/developmental effects) play a big role in the initial 10 risk evaluations and providing protection against them under TSCA obviously means fewer lives lost and less disease, not to mention reduced medical costs and lost earnings,” the environmentalist says.

“A cost-benefit analysis that assigns no value to these benefits is obviously providing an inadequate picture of the need for regulation. I believe a lot of work is underway to quantify the economic impact of non-cancer health risks although I’m not following the details. If EPA makes this a priority, the methodologies will be developed.”

SCHF also argues in the principles that for some chemicals or uses, “[b]anning consumer products presenting unreasonable risks of adverse health effects may often be the only regulatory option that effectively and reliably protects consumers.” Pointing to the example of EPA’s 2018 rule barring the sale of paint stripping products containing methylene chloride to consumers, SCHF adds, “label warnings and personal protective equipment (PPE) are inadequate to protect consumers from products that present unreasonable risks and therefore insufficient to eliminate such risks as required by section 6(a).”

SCHF adds that “[i]ndustrial and commercial uses of chemicals presenting unreasonable risks should also be banned where workplace protections cannot reliably and effectively reduce exposure to levels sufficient to eliminate the unreasonable risk.” SCHF gives as examples of such workplaces as “small businesses with high employee turnover and limited ability to establish and implement effective industrial hygiene controls[,] or where the chemical is used in open processes that cannot practicably be reengineered to reduce worker exposure below levels that present unreasonable risks.”

EPA’s PFAS Funding Would Get \$10 Million Boost From Congress

Pat Rizzuto, Bloomberg Law

<https://news.bloomberglaw.com/environment-and-energy/epas-pfas-funding-would-get-10-million-boost-from-congress?usertype=External&bwid=00000176-8731-dc6b-a17e-af3d59360001&qid=7031430&cti=FGOV&uc=1320000080&et=NEWSLETTER&emc=neve nl%3A62&source=newsletter&item=headline®ion=digest&access-ticket=eyJjdHh0IjoITkVWRSlSImkljoiMDAwMDAxNzYtODczMS1kYzZiLWExN2UtYWYyZDU5MzYwMDAxliwic2InIjoIUUlnYmRjZGllMTRjS2Z3YkhVMnM2bEdEdXZBPSlSlnRpbWUiOiIxNjA4NjM4NjA4IiwidXVpZCI6IjZ2M3pTOW85N256dDQwZnFVVanJjcVE9PXY5YTR0VzBUMjNjZbs9UMzNrWWNKs2c9PSlSlnYiOiIxIn0%3D>

The giant spending and coronavirus relief bill awaiting a final congressional vote would increase the EPA's funding for so-called "forever chemicals" by \$10 million.

The bill ([H.R. 133](#)) the House and Senate appropriations committees negotiated would provide the Environmental Protection Agency at least \$49 million, a \$10 million increase over current funding levels, in order to clean up, work on regulations for, research, and otherwise address per- and polyfluoroalkyl substances, or PFAS.

PFAS are ubiquitously used by many different industries. Some have extraordinarily long lifespans and can cause health problems, including cancer and weakening the immune system. Those concerns have prompted thousands of lawsuits.

- The bill doesn't order the EPA to issue drinking water limits for these chemicals, some of which increasingly are found in groundwater, rivers, wells, and other drinking water sources. But Congress ordered the agency to report its regulatory plans within 60 days of the funding measure becoming law.
- As part of the \$49 million, the bill would allocate the most—"no less than \$20 million"—to the agency's research office, which is developing measurement methods and evaluating ways to dispose of the chemicals.
- The EPA's hazardous waste program would receive at least \$17.5 million.

EPA tightens lead standards after years of resistance

E.A. Crunden, E&E News

<https://www.eenews.net/eenewspm/2020/12/21/stories/1063721247>

EPA is issuing stronger regulations around lead to protect the health of children, after initially resisting calls to strengthen standards.

The agency today announced that it has finalized a rule lowering clearance levels for lead in dust on floors and windowsills following lead removal processes. Lead lingering in dust poses a major health hazard for children, particularly in homes built before 1978, which disproportionately used lead-based paint.

Once abatement actions are taken, EPA requires buildings to be tested and to meet clearance levels before they are deemed safe. Clearance levels under the new rule are now 10 micrograms of lead in dust per square foot for floor dust and 100 micrograms per square foot for windowsill dust. Prior levels were 40 micrograms and 250 micrograms for those areas, respectively.

EPA noted it is not revising dust lead clearance levels for window troughs at this time, and the new standards for floors and windowsills will not apply retroactively.

In a statement, EPA Administrator Andrew Wheeler said children in low-income communities have been particularly vulnerable to "unacceptable levels of lead" in their homes.

"This overdue regulation is yet another example of the Trump Administration's commitment to reduce sources of lead exposure and to provide a healthier environment for our children," Wheeler said.

Housing and Urban Development Secretary Ben Carson similarly said he had "seen firsthand the devastating impact lead exposure can have" and applauded EPA for the move.

The Toxic Substances Control Act directs EPA to regulate lead-based paint activities. Dust lead clearance levels have not been changed since their issuance in 2001, even though lead-contaminated dust is a leading cause of elevated blood lead levels in children. That can cause damage to the brain and central nervous system, as well as lifelong developmental and behavioral issues. There is no level of lead exposure considered safe.

Public health groups petitioned EPA in 2009 to update its rules, but the agency stalled on doing so. In 2018, the 9th U.S. Circuit Court of Appeals ordered EPA to update its lead dust and lead-based paint standards, deeming the agency's delay to be illegal. EPA tightened risk levels for lead in dust in 2019 but did not strengthen clearance standards, a move slammed by environmental advocates ([Greenwire](#), June 21, 2019).

This past October, federal judges again took the agency to task for failing to strengthen the clearance levels (*E&E News PM*, Oct. 27). EPA argued at the time the agency lacked the information to act on adjusting those standards.

The new rule announced today sets clearance levels in line with the risk threshold established in 2019.

Wis. Republicans block tougher PFAS enforcement

E&E News Greenwire

https://www.eenews.net/greenwire/2020/12/21/stories/1063721193?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Agreenwire

Republican state lawmakers on Friday blocked the Wisconsin Department of Natural Resources from enforcing some new regulations designed to keep some PFAS chemicals out of the environment.

The Legislature's GOP-controlled rules committee voted 6-4 along party lines to strip key language from a newly adopted rule limiting the use of firefighting foam containing the "forever chemicals" known as per- and polyfluoroalkyl substances, the *Wisconsin State Journal* reported.

Democrats accused the committee of "neutering" the state's first law aimed at curbing PFAS contamination. But the committee's Republican leaders agreed with industry groups that argued the DNR had overstepped its authority.

The temporary rule, which took effect Dec. 4, outlined steps that testing facilities must take to contain and treat fluorinated foam and effectively prohibits them from discharging water with detectable amounts of PFAS.

Industry groups opposed the rule, which was drafted to comply with a GOP-sponsored law passed last year that restricts the use of PFAS foams to emergency situations and testing facilities with "appropriate containment, treatment, and disposal measures."

The law left it to the DNR to define those treatment and disposal measures.

Darsi Foss, administrator of the DNR's Environmental Management Division, said the amended rule creates a loophole that allows someone to sop up PFAS-laden foam and throw it into any landfill, where PFAS could leak back into the environment.

The vote came after a hearing where the only invited speakers were representatives from Wisconsin Manufacturers & Commerce, the state's largest business lobby; the American Chemistry Council; the Midwest Food Products Association; and the DNR.

Lawsuit Would Overturn EPA Approval Of Dicamba

Chuck Abbott, Successful Farming

<https://www.agriculture.com/news/business/lawsuit-would-overturn-epa-approval-of-dicamba>

The EPA failed to ensure that dicamba can be used safely when it issued a five-year approval of the weedkiller, said a lawsuit that asks a federal appeals court in San Francisco to vacate the EPA registration of the herbicide. Foes say dicamba is overly prone to evaporate from where it is sprayed and to drift onto neighboring fields, orchards, gardens and trees.

"We're in court yet again because for four years, the EPA repeatedly claimed dicamba is safe and for four years, the agency has been dead wrong, resulting in millions of acres of damage," said Nathan Donley of the Center for Biological Diversity. Four groups, including the Center for Biological Diversity, filed the lawsuit on Monday.

EPA administrator Andrew Wheeler announced the five-year approval of dicamba for use on GE cotton and soybeans a week before the presidential election. He said new safeguards, which include a requirement to add a pH buffering agent to sprayer tanks, would reduce the risk of damage. In June, the appeals court in San Francisco vacated the EPA registration of dicamba, ruling the agency underestimated or ignored the risks of the weedkiller. The agency already was at work on conditions for use of dicamba in 2021 and later years.

In June, agrochemical giant Bayer announced a \$400 million settlement of separate litigation claiming crop damage caused by dicamba from 2015 to 2020.

“Rather than do what the law and science requires, the Trump administration has again unlawfully promoted pesticide corporations’ profits over protecting the interests of farmers or the environment,” said George Kimbrell of the Center for Food Safety. “So they are getting what they deserve this holiday season: coal in their stockings and a federal lawsuit.”

The lawsuit says EPA did not consult with other agencies on whether dicamba was a threat to endangered species or their habitats and did not provide sufficient evidence of its conclusion that the herbicide would not cause unreasonable harm.

Dicamba Lawsuit will not Impact 2021 Xtendimax Use, Say Bayer Officials

Gil Gullickson, Successful Farming

<https://www.agriculture.com/news/business/dicamba-lawsuit-will-not-impact-2021-xtendimax-use-say-bayer-officials>

Four groups filed a lawsuit in a federal appeals court on December 21 stating that the Environmental Protection Agency (EPA) failed to ensure that dicamba can be used safely when it issued a five-year approval last October.

EPA’s October 27 decision covered dicamba formulations that include Bayer’s XtendiMax, BASF’s Engenia, and Syngenta’s Tavium.

“Our career staff reviewed significant amounts of new scientific information and carefully considered input from stakeholder groups,” said Andrew Wheeler, EPA administrator, at the time of the decision. He added the EPA determined the registration actions will address the concerns outlined in the in the June (2020) Ninth Circuit Court of Appeals decision.”

However, the four plaintiffs--the Center for Food Safety, Center for Biological Diversity, Pesticide Action Network North America, and the National Family Farm Coalition--disagree with that assessment.

Bayer’s Response

Bayer, which manufactures XtendiMax With VaporGrip Technology that is applied to dicamba-tolerant soybeans and cotton, has issued this statement in response to the lawsuit.

We are reviewing the filing, which has no immediate impact on our ability to bring XtendiMax to growers this season or on growers’ ability to use XtendiMax this season. We look forward to bringing XtendiMax to growers and helping them have a successful 2021 season and beyond. Growers have been clear how vitally important this tool is for their weed-management programs.

On October 27, 2020, the EPA announced the new 5-year registration and product label for XtendiMax.

This new registration decision is based on a significant amount additional data and learnings from recent seasons, and the new product label includes new measures to help growers use the product even more successfully going forward. We believe this new registration and product label effectively address the concerns raised by the court earlier this year.

Bayer stands fully behind our Xtend seeds and our XtendiMax herbicide. We are proud of our role in bringing innovations like these forward to help growers safely and successfully grow healthy crops. We take our stewardship responsibility very seriously, and we will continue to offer trainings, resources, and other support to help ensure growers can use this important crop protection tool even more successfully going forward.

Miss. sues over PFAS in firefighting foam

E.A. Crunden, E&E News

Mississippi is suing several companies over toxic chemical contamination through firefighting foam, the latest in an onslaught of cases around so-called forever chemicals.

State Attorney General Lynn Fitch (R) filed suit yesterday in the U.S. District Court for the District of South Carolina against numerous manufacturers of per- and polyfluoroalkyl substances (PFAS). The companies include 3M Co. and E.I. du Pont de Nemours, as well as the newer DuPont de Nemours formed by a merger with Dow Chemical, and DuPont's spin-off Chemours Co.

The lawsuit accuses the companies of "contamination of the natural resources of the State, including lands, waters, biota, and wildlife," through the release of PFAS into the environment through "the handling, use, disposal, and storage of products" containing the chemicals.

At the crux of the litigation is aqueous film-forming foam (AFFF), which has commonly been used in military and defense practices, as well as in traditional firefighting exercises and crises. Developed in the 1960s, AFFF has historically contained PFOS and PFOA, the most studied PFAS. Those chemicals have been used for their water-repellent properties, but they are also linked to diseases like cancer and other severe health impacts.

Mississippi states in the lawsuit that PFAS manufacturers had knowledge of the health implications associated with those chemicals going back decades. Peer-reviewed literature in 1980 from 3M found humans can retain PFOS in their bodies for long periods of time, while DuPont had knowledge of the toxicity of PFOA "since at least the 1960s," the suit notes.

Investigations of PFAS contamination are ongoing in Mississippi, and the lawsuit states that PFOA and PFOS linked to AFFF have been discovered at multiple sites.

"Additional investigation and testing will undoubtedly uncover further contamination across the State," the lawsuit says.

Mississippi argues that PFAS manufacturers committed a range of acts including negligence, public nuisance and failure to warn about the impacts of their products.

The state wants the companies to foot the bill for all costs relating to investigating and assessing PFAS contamination associated with fluorosurfactant products, as well as remediation, monitoring and restoration costs. Mississippi also wants compensatory damages for harm done to natural resources, along with compensation for the disposal of remaining government inventory of those products.

DuPont did not respond to a request for comment regarding the litigation by publishing time, while Chemours declined to comment.

Sean Lynch, a spokesperson for 3M, said the company "acted responsibly in connection with its manufacture and sale of [AFFF] and will vigorously defend its record of environmental stewardship."

Hundreds of lawsuits have been filed over AFFF and many more over PFAS contamination more broadly. In late November, a town in New York sued 3M, DuPont and Chemours over PFAS contamination in drinking water (Greenwire, Dec. 1).

While the Trump administration has been under pressure to act on PFAS, critics say EPA has stalled on addressing the issue.

President-elect Joe Biden announced yesterday that he will nominate North Carolina Department of Environmental Quality Secretary Michael Regan to head EPA. Regan took on Chemours over PFAS contamination in North Carolina, a record the Biden transition team has touted.

Lawsuit Challenges Re-Approval of Dicamba

Philip Gruber, Lancaster Farming

https://www.lancasterfarming.com/farming/lawsuit-challenges-re-approval-of-dicamba/article_34b8442e-445b-11eb-8840-9b7b5d4f72e0.html

The Center for Food Safety and other groups are suing to overturn the latest approval of dicamba products.

XtendiMax, Engenia and FeXapan lost their registrations because of a court ruling this summer, but in October the Environmental Protection Agency issued new approvals for two of the products and added new rules to prevent drift.

The four groups that won the lawsuit this summer say the use of dicamba in growing soybeans and cotton still poses a hazard.

Though effective against Palmer amaranth and waterhemp, which have developed resistance to glyphosate, dicamba can have problems with wafting away and damaging nontarget plants.

The other plaintiffs in the suit are the Center for Biological Diversity, National Family Farm Coalition and Pesticide Action Network North America.

Groups Argue EPA Failed on Glyphosate

Todd Nealy, Progressive Farmer

<https://www.dtnpf.com/agriculture/web/ag/crops/article/2020/12/21/environmental-ag-worker-groups-epa>

OMAHA (DTN) -- In reapproving registration of glyphosate in January 2020, EPA ignored its own scientific finding that the herbicide may harm nearly all endangered species, environmental and farmworker groups argue in an opening brief last week in a lawsuit filed in the U.S. Court of Appeals for the Ninth Circuit in San Francisco.

The Rural Coalition, Organizacion en California de Lideres Campesinas, Farmworker Association of Florida, Beyond Pesticides and the Center for Food Safety filed a petition for review back in March.

"Given the exponential increase in glyphosate use since its last registration, careful analysis of glyphosate's safety to people who use it and the environment is long overdue," the groups said in their opening brief.

"Rather than rigorously assess the registration based on current science, EPA rubber-stamped Monsanto's assurance of safety, contrary to its statutory duties."

The groups asked the court to vacate EPA's decision.

They allege EPA violated the Federal Insecticide, Fungicide and Rodenticide Act and violated the agency's duties in the Endangered Species Act by not consulting with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service before issuing the decision.

"Petitioners' members include the people who everyday work to bring food to America's tables," the brief said. "They are the frontline of exposure and possible health effects from glyphosate. EPA failed these essential workers by concluding there are no health risks without even assessing workers' exposure to glyphosate and its formulations. When absorbed through the skin, glyphosate enters the bloodstream to cause further harms, such as increasing cancer risk."

When it comes to endangered species, the groups said, the agency did not conduct a full ESA review.

"Here, EPA's cost-benefit analysis consists of a single sentence, where EPA completely fails to weigh the substantial costs of registration: among them, costs to farmers from the epidemic of glyphosate-resistant weeds and costs to wildlife exposed to spraying, especially crucial pollinators and iconic Monarchs," the brief said.

"EPA knows with certainty that glyphosate will likely adversely affect no less than 1,676 species of birds, mammals, fish, plants, amphibians, insects and more."

The herbicide's registration review, which started in 2009, is likely to push into 2021, according to EPA's website.

EPA finalized its decision on glyphosate in January 2020, again stating the herbicide poses no risk to human health and can be used safely with certain drift mitigation requirements.

The agency first proposed the interim measure in April 2019 and accepted public comments until September 2019.

The January 2020 EPA interim decision brought some regulatory clarity to American farmers and chemical companies, amid a storm of global scrutiny of the chemical and a steady march of lawsuits against the herbicide Roundup and its registrant, Bayer.

In early February, both sides in the *Wade v. Bayer* glyphosate case agreed to an indefinite continuance in the trial to allow settlement talks to continue.

In June, Bayer reached a settlement of between \$8.8 billion and \$9.6 billion to resolve current and future litigation on Roundup. The settlement ran into some legal snags.

Bayer acquired Roundup brands as part of its \$63 billion purchase of Monsanto. Bayer continues to maintain that glyphosate is safe, regularly pointing out that the EPA and many other countries' regulatory agencies support glyphosate's continued use.

Agricultural crops genetically engineered to withstand glyphosate have greatly expanded use of the chemistry since 1996. Glyphosate also is used in forestry, urban, lawn and garden applications. Bayer also had glyphosate in its portfolio before acquiring Monsanto.

That broad use has drawn worldwide attention to the herbicide and its safety.

Though glyphosate was developed by Monsanto, it is off-patent and sold by many agriculture companies as one of the most widely used herbicides in the world. It came to market in 1974 under Monsanto's Roundup label for control of perennial and annual weeds in non-crop and industrial areas. In 2018, California regulators failed in an attempt to label glyphosate products as "known to cause cancer."

Read the full brief here: <https://www.centerforfoodsafety.org/...>

With chlorpyrifos on its way out, what's next for Oregon farmers?

Sierra Dawn McClain, Capital Press

https://www.capitalpress.com/state/oregon/with-chlorpyrifos-on-its-way-out-whats-next-for-oregon-farmers/article_432a6ea6-43cf-11eb-917e-7b440538a32f.html

SALEM — As Oregon farm regulators move to phase out most uses of the pesticide chlorpyrifos by the end of 2023, researchers are scrambling to find alternatives.

The state Department of Agriculture last week classified chlorpyrifos as a restricted use pesticide.

Chlorpyrifos is used to control a broad spectrum of insects in more than 50 crops statewide, but studies showed it may have harmful neurological effects.

Growers say alternatives are urgently needed, but research could take one to five years per pest per crop, followed by a years-long registration process — and researchers say the state isn't supporting them with sufficient funding.

"Coming up with new modes of action has gotten harder and harder," said Ian Grettenberger, an entomologist at the University of California-Davis Cooperative Extension.

Grettenberger received a grant when California's Legislature, after voting last year to take away chlorpyrifos, invested millions of dollars in researching alternatives.

Oregon, in contrast, has set aside little funding.

Silvia Rondon, Oregon State University Extension entomology specialist, recently received a \$162,794 USDA Specialty Crop Block Grant to explore chlorpyrifos alternatives.

"It's a great first step," said Rondon.

But the money won't last long. Rondon plans to split \$162,794 five ways among team members.

On the OSU team, Rondon will focus on corn, Stuart Reitz will study onions, Christopher Adams will study pears, Navneet Kaur will study grass seed and Danielle Lightle will study mint and clover.

Some early explorations look promising.

Onion growers, for example, rely on chlorpyrifos to control maggots.

"For those of us that work with onions and garlic, that (decision) was like a — a dagger," said Rob Wilson, director of intermountain research at the University of California's Tulelake Office.

But early research has shown treating onion seeds with neonicotinoids can prevent maggots. The seed treatments, Wilson said, are "very effective," but they are costly and growers must plan months in advance.

This reflects a trend: "alternative" doesn't always mean "replacement."

Most alternatives, according to Daniel Putnam, a UC-Davis plant scientist, eat a grower's profit margin.

Many have narrow application requirements. Some can only be applied via irrigation, must be tilled in, are effective exclusively at low temperatures or can only be used twice annually.

For decades, the U.S. has been moving away from broad spectrum and toward target pesticides, which kill a narrow set of pest species.

With chlorpyrifos disappearing, scientists fear pests may develop resistance to other products.

"Using the same material again and again could cause issues with resistance," said Rachael Long, a pest expert at UC Cooperative Extension.

One reason few alternatives exist in Oregon is because it's a specialty crop state. Investors have a financial incentive to back pesticide research for commodities such as soybeans, but not for niche crops.

When the Oregon House voted to ban chlorpyrifos during the last session, farm groups say many members voted under the false assumption there were numerous effective alternatives.

In the 2020 short session, Jonathan Manton, a lobbyist for Mountain Grown Herbs and the Oregon Organic Coalition, citing a letter drafted by environmental group Friends of the Earth, told legislators there were already 67 safer pesticides available for Christmas trees, 178 for apple trees and 98 for turf and grass seed.

A third-generation farmer who testified, Brenda Frketich, said she later talked to Manton, traced citations, called 39 researchers, and to date, still hasn't obtained that list of alternatives.

Manton told the Capital Press Monday that he obtained the letter from a previous Oregon Legislative Information System, or OLIS, posting, that he did not know the letter's origins at the time and did not verify its accuracy.

The letter, obtained by the Capital Press through OLIS and reviewed by the Oregon Farm Bureau, contains multiple errors, including duplicated names among the signers.

"It was disheartened this letter had so much weight," said Frketich.

The bill passed in the Oregon House and stalled in the Senate during the Republican walkout. ODA ultimately took charge, crafting a phaseout plan.

Frketich grows hazelnuts and grass seed. The Oregon Seed Council projects that without chlorpyrifos, seed producers could experience a 40% loss, costing the industry \$160 million.

Agricultural leaders say farmers should urge their legislators and state agencies to fund research into alternatives.

AGs say EPA rule boosts toxic exposure risk for farmers

Marc Heller, E&E News

https://www.eenews.net/greenwire/2020/12/18/stories/1063721095?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Agreenwire

Attorneys general in California, New York and three other agricultural states are mounting a legal challenge to EPA's latest effort to ease worker protection standards for pesticides.

In a lawsuit filed in the U.S. District Court for the Southern District of New York, the state attorneys said regulations released by EPA in October would put workers, farmers and others at increased risk of exposure to dangerous weed killers and insecticides.

At issue are the "exclusion zones" EPA established at farms, aimed at preventing exposure to unprotected people. The zones, extending 100 feet around pesticide application sites, were added to the agency's worker protection standard in 2015, during the Obama administration.

EPA's final regulations remove provisions that apply to areas off the farm in question — areas that are too hard for states to enforce, the agency said.

Farmers and their family members are also exempt under the EPA rules. The agency has said the updated regulations will be more workable, while protecting people from potential exposure (Greenwire, Oct. 29).

In their complaint, the state attorneys called the regulation "unjustified and unwarranted" and said the agency's own cost-benefit analysis doesn't support the change.

The regulation, the states said, "needlessly increases the risk of exposure to harmful pesticides by permitting pesticide handlers to continue pesticide applications despite the presence of farmworkers or other persons within the area immediately surrounding the application equipment."

Other states joining the case are Illinois, Maryland and Minnesota.

In a statement, Maryland Attorney General Brian Frosh (D) suggested EPA is shirking its responsibility.

"It is EPA's job to protect farmworkers, their families and others who are exposed to pesticides. These regulations prioritize killing bugs over protecting people," Frosh said.

In New York, about 7.2 million acres — a quarter of the state — is covered by farms. Nearly 3 million gallons of liquid pesticides and 24.3 million pounds of solid pesticide were applied there in 2013, according to the complaint, citing the state Department of Environmental Conservation.

In California, the nation's leading farm state, 204.7 million pounds of pesticide were applied on 104.3 million acres cumulatively, the complaint said. That state changed its own worker protection standard in 2017 to align with EPA's 2015 regulations, meaning the new federal rules will create confusion, according to the lawsuit.

State agriculture departments have applauded EPA's changes, however, saying they'll clarify the rules and free state regulators of the difficult task of enforcing rules on off-farm property.

Other elements of the regulation would allow suspended pesticide applications to resume when unprotected individuals leave the exclusion zone.

The National Association of State Departments of Agriculture has supported EPA's moves. The American Public Health Association has opposed them.

The pendulum is the pits: Can the United States make enduring regulations?

Phillip A. Wallach, Brookings

A major focus of Barack Obama's administration was reversing the regulatory program of the George W. Bush administration. A major focus of Donald Trump's administration was reversing the regulatory program of the Obama administration. And a major focus of Joe Biden's incoming administration will be reversing the deregulatory program of the Trump administration. Back and forth and back again we go.

Well, so what? Isn't this just part of what we call democratic accountability? Haven't things always been thus?

While we ought to expect some kind of policy pendulum that tracks changes in partisan control of the White House, the truth is that things have not always been this volatile. The 21st century has been an infamously partisan political era, but regulation itself has also become a far more partisan issue. When we think only about the familiar Bush-Obama-Trump-Biden reversals, we are likely to forget that regulatory state-building forged ahead under Lyndon Johnson and then kept on forging ahead under Richard Nixon, or that old-fashioned deregulation of industries like railroads, trucking, commercial aviation, and financial services began in earnest under Jimmy Carter and continued apace under Ronald Reagan. The rise and reliance on cost-benefit analysis was a thoroughly bipartisan affair. And even in George W. Bush's presidency, there was more enthusiasm for building on market-based regulatory innovations of the past than for simply targeting the actions taken under Bill Clinton.

Throughout the earlier period, it was taken for granted that enduring regulatory change would be driven, first and foremost, by legislation. Arriving at the compromises that made legislation possible was often hard work; for example, the Clean Air Act Amendments of 1990 came after nearly a decade of Congress putting forth proposals, and the Gramm-Leach-Bliley Act of 1999, which reconfigured American banking law, was the result of a reform campaign that dated back to the 1980s. While presidents and their administrative agencies hardly sat around waiting for these legislative changes to come through, there was nevertheless a presumption that the most significant changes in regulatory programs would have to be rooted in statutory amendments.

Today, however, there is a sense of despair about the prospects for legislative changes to our regulatory programs. Democrats assume Republicans will oppose every regulation, however beneficial; Republicans assume Democrats always want more regulation, whatever its effects on the economy. That mutual suspicion (which is often unfounded) leads presidents and those who would influence them to think almost exclusively in terms of unilateral executive actions, including executive orders, guidance documents, and rulemakings. All of these can reinterpret existing regulatory statutes to align better with the current administration's policy preferences—but none can actually change the law on the books, which often leads to serious difficulties and protracted litigation.

Climate change policy provides an outstanding, but not entirely anomalous, example of the dynamic that has resulted. After the Democrat-controlled Congress failed to push a climate bill through in 2010, the Obama administration turned to the Clean Air Act to limit greenhouse gas emissions. That law's language was broad enough to encompass carbon emissions, but at the same time its structure always made it an awkward fit for combating climate change, since its built-in remedies were designed to mitigate localized concentrations of pollution rather than reduce American contributions to global ambient levels of carbon. The administration nevertheless proceeded with a variety of regulatory actions, the most prominent of which was the Clean Power Plan finalized in 2015 but stayed by the Supreme Court in February 2016 pending further litigation. Turning back these Obama climate policies was a major focus of the Trump administration, which first put the Clean Power Plan in suspended animation, then formally rescinded it and replaced it with the Affordable Clean Energy rule in June 2019. Now, those actions are being litigated, and they will probably be held in stasis and replaced by the Biden administration. It seems not entirely far-fetched to imagine that, four years from now, we could see the Biden administration's rules on this front caught up in the courts, only to be targeted for replacement by the next administration.

Whatever the policy or legal merits of any of these rules, this is no way to make policy in the world's leading economy. Regulatory uncertainty is the bane of sound planning and long-term capital investments, of the sort that are crucial in the power sector and others. And yet there no longer seems to be the will in Congress to tackle major regulatory issues. Arguably, we have to go back to the end of the Obama administration for the last major statutory changes to regulation: the Lautenberg Chemical Safety Act of 2016 significantly updated the Toxic Substances Control Act, and Congress passed a law setting up a federal regime for the labeling of genetically modified organisms in the food supply. Perhaps the most significant regulatory change that Congress enacted into law during the Trump administration was a relatively minor amendment to the Dodd-Frank Act aimed largely at easing regulatory burdens on small banks. Regulatory process reforms that many (including me) saw as having bright prospects in Congress never ultimately made it as far as the Senate floor, although some of their substance was later put into effect through executive branch actions.

One might try to defend the status quo by arguing that the broad regulatory statutes already on the books sufficiently empower administrative agencies to update their policies in response to a changing world. In other words, the Environmental Protection Agency (EPA) already possesses ample legal powers to address climate change because it is empowered to protect the general welfare from airborne threats. The Federal Communications Commission (FCC) can regulate new internet technologies as they emerge, because the Communications Act of 1934 is written to encompass all kinds of media, even those unbeknownst to the enacting Congress.

There are surely cases when such executive-led statutory adjustment will be sufficient. But the dizziness induced by our pendulum over the past two decades is itself a sufficient rebuttal to those who argue that our current statutory frameworks are fine just as they are now. Whereas new statutes could put new regulations on a sound legal foundation, reinterpreting old ones inevitably stokes political and legal controversies. The FCC does clearly have broad power—but it is not at all clear that its existing power allowed it to prescribe a rule of net neutrality, as it did in its Open Internet Order of 2015. The Clean Air Act may well give the EPA power to regulate greenhouse gas emissions, but without amendment it cannot give the agency the power to set a universal price on carbon emissions, which is the policy that would best suit the nature of the problem. Lacking statutory amendments, we end up in a world of kludgeocracy, where policies are both poorly designed and politically illegitimate.

But as obvious as the shortcomings of our wildly swinging regulatory pendulum are, the sense that legislation is impossible to push through threatens to become a self-fulfilling prophecy. Well before the election, we have seen would-be advisors of the Biden administration focus on unilateral executive actions. In July, The American Prospect offered “The 277 Policies for Which Biden Need Not Ask Permission.” In August, the Sabin Center for Climate Change Law published a white paper, “Climate Reregulation in a Biden Administration,” which set forth 13 executive actions, dozens of proposals for the EPA and the Departments of the Interior, Energy, and Transportation, and more. It assumed that “a divided Congress” would make legislation unlikely, and therefore focused on the executive branch. I don't mean to criticize these reports for their focus. Indeed, given the prevailing mindset in Washington, their realism is likely to make them more helpful to policymakers in the new administration. Still, the more that policy entrepreneurs confine themselves to thinking in terms of executive branch actions, the harder it will be to chart a path toward politically durable regulatory policies.

EPA allows voluntary labeling of disinfectants' inerts

Inside TSCA

<https://insideepa.com/tsca-takes/epa-allows-voluntary-labeling-disinfectants-inerts>

EPA has quietly published a policy that allows manufacturers to voluntarily disclose the inert ingredients in their disinfectant products that are used to mitigate the spread of the coronavirus -- either on their product labels or through a website that is linked on the products' labels, a move sought by both industry and environmentalists.

Toxics chief Alex Dunn wrote in a Dec. 10 memo that this new voluntary labeling process -- which took effect Dec. 15 -- has been requested by registrants of pesticide products but had not previously been adopted due to the challenges posed by limited label space, “numerous” alternate formulations for products, and the potential for misbranding.

“By implementing this new policy, EPA is being responsive to external stakeholders’ request to disclose all ingredients -- active and inert -- on EPA-registered antimicrobial product labels,” the memo states. “EPA will continue to work with registrants to ensure that pesticide labels meet the statutory and regulatory requirements.”

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which governs EPA registration of antimicrobial products, the agency does not require inert ingredients to be identified in ingredient statements except in cases where such substances pose hazard or risk.

For example, the agency has previously required labeling of “petroleum distillates, xylene, or xylene range aromatic solvents” when they’re present in more than 10%; sodium nitrate when it’s present in more than 0.1%; and inert ingredients of toxicological concern, formerly known as List 1 Inerts.

“EPA’s new policy applies to voluntary identification of inert ingredients using alternate nomenclature and not to cases where EPA directs registrants to list particular inert ingredients because of risk-based or hazard-based reasons,” the Bergeson Campbell law firm says in a Dec. 18 posting.

The policy will allow registrants “voluntarily to disclose all inert ingredients more efficiently in response to the request of retailers, states, and industry,” the firm adds

EPA’s long-standing policy has been that “if a registrant wants to list a particular inert ingredient in the ingredient statement, the registrant should list all inert ingredients directly below the ingredient statement in descending order by weight” as “a partial listing on the label could be misleading.”

But such policies have drawn criticisms from environmentalists. For example, Beyond Pesticides earlier this year petitioned policymakers to “urge EPA use its legal authority to require disclosure of all ingredients on pesticide labels to protect public health.”

“Protecting ourselves from COVID-19 requires not only that we avoid contact with the virus, but also that we avoid exposing ourselves to chemicals that may disrupt our immune or respiratory systems. But when it comes to pesticide products--and disinfectants are pesticides--we encounter once again the problem of so-called “inert,” or nondisclosed, ingredients,” the group said.

Similarly, the Household & Consumer Products Association (HCPA) in a Dec. 15 statement welcomed EPA’s new policy.

“Now more than ever, consumers want to know what ingredients make up the products they use to clean and disinfect their homes,” said Steve Caldeira, the group’s president and CEO. “This action by the EPA makes it easier for consumers to access that information. We appreciate the Agency’s continued commitment to transparency, and hope this will ultimately allow manufacturers to list ingredients on a product’s label if they choose.”

EPA adds that while the policy currently applies to antimicrobial products, “the Agency may consider expanding its process to conventional pesticides and biopesticide product in the future.”

The agency has previously provided other relief regarding inert ingredients. Early in the pandemic, the agency adopted rules allowing disinfectant manufacturers to bypass some reporting requirements for an initial list of 280 inert ingredients in order to ease supply of products.

Farmworkers and Conservationists Ask Court to Remove Monsanto’s Roundup from the Market

Beyond Pesticides

<https://beyondpesticides.org/dailynewsblog/2020/12/farmworkers-and-conservationists-ask-court-to-remove-monsantos-roundup-from-the-market/>

Opening arguments and evidence were filed by a coalition of farmworkers, farmers, and conservationists last week in litigation challenging the U.S. Environmental Protection Agency’s (EPA) re-approval of glyphosate, best known as the active ingredient in Monsanto’s “Roundup” pesticides. The lawsuit charges that the Trump Administration unlawfully ignored cancer risks and ecological damage of glyphosate.

Represented by the Center for Food Safety (CFS), plaintiffs, including the Rural Coalition, Farmworker Association of Florida, Organización en California de Lideres Campesinas, and Beyond Pesticides, filed the federal lawsuit in the Ninth Circuit Court of Appeals in March. The groups seek to have the pesticide prohibited from use or sale because of its unlawful approval.

“Farmworkers are on the frontlines of nearly every health and environmental crisis, from the COVID-19 pandemic to climate change, and are particularly at risk of health impacts from pesticide spraying,” said Amy van Saun, senior attorney at CFS. “EPA failed these essential workers. It rejected evidence that glyphosate causes cancer and entirely failed to assess the main way people are exposed at work, through their skin.”

The court filing includes volumes of evidence showing how EPA ignored glyphosate’s health risks, including cancer risks, to farmworkers and farmers exposed during spraying. The evidence filed also shows how EPA disregarded glyphosate’s ecological impacts and that EPA failed to account for the costs to farmers from glyphosate-resistant “superweeds” and off-field drift damage.

“Farmworkers and farmers are the backbone of our food system. As we demonstrate in this filing, they are the first—but not the last—to bear the huge costs of EPA’s deeply flawed and unlawful re-approval of glyphosate, while corporate shareholders of Monsanto-Bayer benefit,” said John Zippert, chairperson of the Rural Coalition, the lead petitioner in the case.

While EPA once recognized glyphosate might cause cancer, it now finds this possibility to be “not likely.” In contrast, the world’s foremost cancer authorities with the World Health Organization determined in 2015 that glyphosate is ‘probably carcinogenic to humans.’ In June, Bayer agreed to pay up to \$10.9 billion to roughly 125,000 people in thousands of lawsuits arguing Roundup was responsible for their non-Hodgkin lymphomas, a cancer that originates in lymph tissue. The plaintiffs have prevailed in all the trials so far, with victims awarded \$25-80 million in each case.

“Farmworkers cannot wait any longer for EPA to ban glyphosate—a pesticide that risks their health and the health of their children,” said Jeannie Economos of the Farmworker Association of Florida, a plaintiff in the case. “The public now knows that farmworkers are ‘essential workers,’ but they have always been essential. Their work feeds the people of this country and they deserve to be protected from a pesticide known to cause chronic diseases.”

EPA also issued the challenged re-approval without any consideration of the dire risks glyphosate poses to threatened and endangered species. A belated EPA assessment—which was required by law before the approval, not after—has now confirmed these risks, finding that glyphosate will likely have adverse effects on at least 1,676 different species protected by the Endangered Species Act (93% of those exposed) and on 96% of their critical habitats. Instead of ensuring this pesticide will not cause the extinction of these species, EPA’s decision allows it to be sprayed on 285 million acres of farmland a year, with 21 million pounds applied to forests, parks, lawns, schoolyards, and roadways.

Additionally, the lawsuit alleges EPA failed to account for the risks glyphosate poses to honey bees, other pollinators, and the iconic Monarch butterfly. Monarch butterflies face possible extinction due in part to glyphosate’s near-eradication of their critical host plant, common milkweed, from Midwest farm fields. On December 15th, in response to a 2014 CFS petition, the U.S. Fish and Wildlife confirmed the Monarchs’ precarious state, concluding that Monarchs warrant protected status under the Endangered Species Act (ESA), though formal listing was postponed to 2024 due to the Service’s backlog of other ESA cases.

“Glyphosate use and resulting exposures represent a serious threat to the safety of people and the environment, including many hundreds of endangered species—facts astonishingly ignored by regulators,” said Jay Feldman, executive director of Beyond Pesticides, a plaintiff in the case. “It is unfortunate that it takes a lawsuit like this to force EPA to carry out its responsibility in the face of a mountain of scientific findings that document glyphosate’s harm,” Mr. Feldman added.

The lawsuit comes after EPA earlier this month released its draft biological evaluation (BE) of glyphosate. The assessment, covered in an earlier Daily News, indicates that use of this ubiquitous herbicide likely threatens nearly every animal and plant species on the U.S. list of threatened and endangered species — 93% of them.

The evidence filed in the lawsuit also reveals EPA's failure to assess the substantial costs incurred by farmers due to the glyphosate-resistant weed epidemic unleashed by massive use of this herbicide on genetically-engineered crops, as well as plant and crop damage from glyphosate drift.

"The industry's response to glyphosate-resistant weeds has been crops resistant to additional herbicides like dicamba, which has caused enormous drift damage and still more intractable weeds," said Bill Freese, science policy analyst at CFS. "EPA has done nothing to halt or even slow this toxic spiral of increasing resistance and herbicide use."

Glyphosate use has been steadily increasing with the introduction and growth of genetically engineered, herbicide-tolerant crops. As public exposure to the chemical grows, there is a correlated increase with chronic diseases. Organic land management in agriculture and lawns, parks and playing fields has grown to an economically viable alternative to chemical-intensive, genetically engineered crop production and conventional turf management, despite efforts to weaken organic law. For action that can be taken to ban glyphosate and adopt organic practices and policies in states and communities, see Beyond Pesticides action Ban Glyphosate-Adopt Organic campaign.

Farmers, Conservation Groups Challenge EPA's Unlawful Re-approval of Dangerous, Drift-Prone Dicamba Pesticide

George Kimbrell, Center for Biological Diversity

<https://biologicaldiversity.org/w/news/press-releases/farmers-conservation-groups-challenge-epas-unlawful-re-approval-of-dangerous-drift-prone-dicamba-pesticide-2020-12-21/>

SAN FRANCISCO-- Four public interest groups filed a lawsuit today challenging the Environmental Protection Agency's rushed re-approval of products containing the dangerous, drift-prone dicamba pesticide.

Over the past four years the dicamba products sprayed "over the top" of soybean and cotton crops genetically engineered to resist the pesticide have caused drift damage to millions of acres of soybeans as well as orchards, gardens, trees and other plants on a scale unprecedented in the history of U.S. agriculture.

The new lawsuit follows the groups' successful prior cases, decided in June, in which the court ruled the EPA's previous approval to be unlawful and struck it down.

"Less than six months ago, the Ninth Circuit resoundingly rejected Monsanto's and EPA's arguments about this pesticide, detailing its substantial drift harms," said George Kimbrell, legal director of Center for Food Safety and counsel in the case. "Rather than do what the law and science requires, the Trump administration has again unlawfully promoted pesticide corporations' profits over protecting the interests of farmers or the environment. So they are getting what they deserve this holiday season: coal in their stockings and a federal lawsuit."

As today's lawsuit explains, the EPA again failed in its legal duties to ensure that the pesticide would not cause unreasonable harm to farmers and farming communities as well as to the environment and hundreds of endangered species.

In its June 2020 56-page decision, the court explained that the EPA violated the law when it failed to consider and account for the "enormous and unprecedented damage" caused by dicamba drift — damage that has "torn apart the social fabric of many farming communities." However, just days before the November presidential election the EPA rushed to reapprove the dicamba products for five years. This is the third time the agency has registered these products, each time with additional restrictions that have failed to stem devastating drift.

"We're in court yet again because for four years the EPA has repeatedly claimed dicamba is safe, and for four years the agency has been dead wrong, resulting in millions of acres of damage," said Nathan Donley, a senior scientist at the Center for Biological Diversity. "The Trump administration keeps insisting it wants to grant 'certainty' to farmers, and it's certainly done that. Farmers across the U.S. are now certain dicamba use poses an extremely high risk of damaging neighboring crops, orchards and forests."

"It's absurd that we have to go to court to force EPA to do its job," said Kristin Schafer, executive director of Pesticide Action Network North America, a plaintiff in the case. "Millions of acres of crops have already been damaged by

dicamba. This herbicide is hurting farmers and is already creating more resistant weeds, accelerating a dangerous pesticide treadmill.”

“The Environmental Protection Agency clearly has no intention of living up to its name or its mission,” said Jim Goodman, a retired farmer and National Family Farm Coalition board president, a plaintiff in the case. “The agency continues to work on behalf of corporate profits over the health and wellbeing of farmers, farmworkers and their communities.”

Represented by Center for Food Safety and Center for Biological Diversity, plaintiffs in the case include National Family Farm Coalition and Pesticide Action Network North America.

Background:

According to agronomists, dicamba has caused the most extensive drift damage ever seen in the history of U.S. agriculture. In just four years of use, it has injured at least 5 million acres of soybeans, decimated fruit orchards and vegetable farms, and damaged trees, backyard gardens and natural areas throughout much of rural America.

Recent findings also suggest dicamba endangers human health. Earlier this year scientists at the National Institutes of Health found that use of dicamba can increase the risk of developing numerous cancers, including liver and intrahepatic bile duct cancers, acute and chronic lymphocytic leukemia and mantle cell lymphoma.

In separate actions, thousands of farmers have sued Monsanto and BASF for dicamba drift damages. These cases were consolidated into class-action lawsuits that were settled earlier this year for \$400 million. In a separate lawsuit, a jury awarded Missouri peach farmer Bill Bader \$15 million for dicamba damage to his peach orchard, and an additional \$250 million in punitive damages.

Internal company memos released in the course of the Bader lawsuit revealed that even as Monsanto and BASF publicly denied that their products posed a major drift threat, they were internally projecting thousands of dicamba drift complaints over the first five years of use.

CFS and many others urged the EPA as early as 2010 to reject Monsanto's petition to approve dicamba for use on the company's dicamba-resistant soybeans and cotton, warning of precisely the extensive drift damage that has now occurred, as well as the rapid emergence of dicamba-resistant weeds that is already underway on America's farmlands.

The EPA ignored those warnings, relying entirely on faulty, Monsanto-generated data in concluding drift injury would not occur, and on an ineffective herbicide-resistant management plan.

EPA Releases Proposed Amendments to TSCA Fees Rule

Lynn L. Bergeson and Carla N. Hutton, Bergeson & Campbell TSCA Blog

<http://www.tscablog.com/entry/epa-releases-proposed-amendments-to-tsca-fees-rule>

On December 21, 2020, the U.S. Environmental Protection Agency (EPA) released a proposed rule that would amend the 2018 Toxic Substances Control Act (TSCA) fees rule. According to EPA, the proposed rule “reflects real-world situations, narrows the broad scope of current requirements, significantly reduces the burden on American businesses, and increases the flexibility for surrounding TSCA fees requirements.” Under TSCA, EPA collects fees from chemical manufacturers and processors to help fund implementation to ensure that public health and the environment continue to be protected. TSCA requires EPA to review its fees every three years and, after consulting with parties potentially subject to the fees, to adjust the fees if necessary. The proposed updates include:

- Narrowing the scope of the TSCA fees rule by exempting importers of articles containing a chemical substance, companies that produce a chemical as a byproduct or manufacture or import as an impurity, companies that produce a chemical in *de minimis* amounts, companies that use chemicals solely for research and development

(R&D) purposes, and companies that manufacture a chemical that is produced as a non-isolated intermediate from fees;

- Using cost data gathered over the past two years, instead of estimates, to update the fee calculations;
- Ensuring fees are fairly and appropriately shared across companies by proposing a production-volume based fee allocation and including export-only manufacturers for EPA-initiated risk evaluations;
- Allowing for corrections to be made to the list of manufacturers subject to fees for EPA-initiated risk evaluations after the final list is published, ensuring the accuracy of the list;
- Increasing flexibility for companies by extending the amount of time to form consortia to share in fee payments;
- Ensuring that EPA can fully collect fees and enabling companies to prepare better for paying fees by allowing payments in installments for EPA-initiated and manufacturer-requested risk evaluations; and
- Adding new fee categories associated with new chemicals activities.

Comments will be due 45 days after EPA publishes the proposed rule in the *Federal Register*. More information will be available in a forthcoming memorandum that will be posted on our website.

Could PFAS levels in blood impact effectiveness of COVID-19 vaccine?

Steve Devane, News & Record

https://greensboro.com/news/crime/could-pfas-levels-in-blood-impact-effectiveness-of-covid-19-vaccine/article_aa44d44a-432b-11eb-b6fc-c7132ffa005e.html

Residents who have been exposed to GenX and similar compounds should take extra precautions to protect themselves against COVID-19, scientists who study the chemicals say.

The scientists encouraged those who have been exposed to the chemicals to get vaccinated for COVID-19, even though the exposure might limit the vaccine's effectiveness.

The Environmental Working Group, a nonprofit organization in Washington, D.C., hosted an online presentation Thursday about how per- and polyfluoroalkyl substances (PFAS) are known to have toxic effects on the immune system, which can make vaccines less effective.

Linda Birnbaum, former director of the National Institute of Environmental Health Sciences and National Toxicology Program; Jamie DeWitt, associate professor of pharmacology and toxicology at East Carolina University; and Tasha Stoiber, senior scientist with the EWG, also talked about how communities that are exposed to high levels of PFAS chemicals may be more vulnerable during the pandemic.

EWG reported this month that the Centers for Disease Control and Prevention is investigating the link between PFAS and the decreased effectiveness of the COVID-19 vaccines.

The CDC's Agency for Toxic Substances and Disease Registry said in June that it is concerned over how PFAS exposure might impact the risk of COVID-19 infection.

The PFAS group of chemicals has been in use for decades. The compounds have been used to make consumer products like cookware, food packaging and stain repellents.

Birnbaum said that more than 9,000 PFAS chemicals have been intentionally synthesized.

"They are everywhere," she said.

The CDC says research shows that exposure to high levels of certain PFAS compounds may lead to an increased risk of kidney or testicular cancer and other harmful health effects.

A PFAS chemical called GenX and other similar chemicals have contaminated hundreds of private wells in Bladen and Cumberland counties. GenX is manufactured by the Chemours company at its Bladen County plant. The chemical also is a byproduct of processes at the facility.

In animal studies, GenX has been linked to cancer and other diseases, but it isn't known if the effect is the same on humans. Chemours officials have said the amount of GenX found in wells around its plant is not harmful.

In response to a question about the areas contaminated by GenX and high rates of COVID-19, DeWitt encouraged everybody to follow recommended public health guidelines of wearing masks, staying at least 6 feet away from other people, and washing hands frequently.

"If you live in an area with known concentrations of PFAS, be even more diligent about washing your hands, wearing a mask and social distancing," she said. "Try to avoid coming into contact with people who may increase your risk of contracting COVID."

DeWitt talked about studies that showed how exposure to PFAS chemicals can impact the immune system.

"Some people who are exposed to PFAS will have suppressed immune systems," she said. "Some people who are exposed to PFAS will end up having immune systems that go overboard."

DeWitt some people might get sick more often, and some might not.

"But all people who have these effects on their immune systems after PFAS exposure will have a higher risk of developing diseases compared to people who don't have these effects on their immune systems," she said.

DeWitt said those who have been exposed to PFAS compounds should still get vaccinated.

"That vaccine is going to give your immune system an additional tool to fight COVID," she said.

Stoiber agreed, saying it's critical for as many people as possible to get vaccinated to end the pandemic.

"It might be important for those that do have higher PFAS in their bodies to be prioritized to be vaccinated because they do have this increased risk of severe illness," she said.

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